510(k) Summary

K102639

DEC 1 2010

1. **Contact Person:**

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Regulatory Affairs
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Date of Summary Preparation: 11/30/2010

2. **Name of Medical Device**:

Proprietary Name:	SL3
Common/Usual Name:	Surgical Laser System
Classification Name:	Laser, Surgical (21 CFR 878.4810 Product Code GEX)

3. **Substantial Equivalence:**

The SL3 is substantially equivalent to the following commercially marketed product

Predicate Device	**Company**	**510(k) No.**
SoftLase Pro	Zap Lasers, LLC	K091796
Styla	Zap Lasers, LLC	K081214

4. **Description of Device:**

The SL3™ is a Class IV soft-tissue diode laser that can be used for a wide variety of soft-tissue procedures. This device uses a Gallium, Aluminum, Arsenic (GaAlAS) diode for the active medium, producing laser energy at 810 nanometer wavelength. Laser technology has been steadily evolving, allowing doctors to provide less invasive treatment for many dental procedures, both preventative and restorative. The SL3™ is designed to be compact, portable, reliable and user friendly. It provides the practitioner with a versatile instrument for applications ranging from excisions to vaporization of tissues. The diode laser energy is delivered through optical fiber in the hand piece to the removable fiber tips. The system may be utilized for a wide variety of surgical and cosmetic procedures.

5. Intended Use

The SL3™ is intended to be used for oral soft tissue surgery, including: biopsies, hemostatic assistance; treatment of apthous ulcers; frenectomy; gingival incision and excision; gingivectomy; gingivoplasty; incising and draining of abscesses; operculectomy; removal of fibromas; soft-tissue crown lengthening; sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) and tissue retraction for impressions.

6. Summary of Technological Characteristics

Name	Discus Dental, LLC --- SL3	Zap Laser, LLC --- Softlase Pro	Zap Laser, LLC --- Styla
510(k) number	K102639	K091796	K081214
Type of laser	Diode laser	Diode laser	Diode laser
Wavelength	808 ± 10 nm	808 ± 5 nm	808 ± 5 nm
Max output power	3.0 Watt	2.0 Watt	2.0 Watt
Power requirements	100-240 VAC, @ 50-60 Hz, 1A	100-240 VAC, @ 50-60 Hz, 1A	90-240 VAC @ 50-60 Hz, 0.8A
Battery	Corded or battery operation	Corded – no battery	Battery operated
Operation mode	Continuous wave and pulsed	Continuous wave and pulsed	Continuous wave and pulsed
Delivery system	400 um core quartz fiber	400 um core quartz fiber	400 um core quartz fiber
Fiber	FC connector to handpiece - Disposable tip magnetically attached to handpiece	SMA 905 connector to handpiece - perpetual fiber	Disposable tip magnetically attached to handpiece

Fiber aiming beam	5 mw diode laser, 650 nm	5 mw diode laser, 650 nm	5 mw diode laser, 650 nm
Activation means	Wireless foot switch - takes 2 AA batteries	Corded foot switch	Wireless foot switch - takes 2 AA batteries
Interface	Color LCD touch-screen GUI on desk unit displays 8 pre-set procedures or manual control to set power and laser mode (continuous or pulse)	Color LCD touch-screen GUI on desk unit displays 8 pre-set procedures or manual control to set power and laser mode (continuous or pulse)	OLED on handpiece displays 8 pre-set procedures or manual control to set power and laser mode (continuous or pulse)
Diode Assembly	3 watt single emitter diode lasing at 808 nm	2.5 watt single emitter diode lasing at 808 nm	2.0 watt single emitter diode lasing at 808 nm
Cooling system	Heat sink	Fan	Heat sink
Laser diode power supply	External	Internal	External
Intended Use / Indications for Use	-Excision and Incision Biopsies -Hemostatic assistance -Treatment of Apthous Ulcers -Frenectomy -Frenotomy -Gingival Incision and Excision -Gingivectomy -Gingivoplasty -Incising and Draining of Abscesses -Operculectomy	-Excision and Incision Biopsies -Hemostatic assistance -Treatment of Apthous Ulcers -Frenectomy -Frenotomy -Gingival Incision and Excision -Gingivectomy -Gingivoplasty -Incising and Draining of Abscesses -Operculectomy	-Excision and Incision Biopsies -Hemostatic assistance -Treatment of Apthous Ulcers -Frenectomy -Frenotomy -Gingival Incision and Excision -Gingivectomy -Gingivoplasty -Incising and Draining of Abscesses -Operculectomy

	-Oral Papillectomy -Removal of Fibromas -Exposure of unerupted teeth -Soft Tissue Crown Lengthening -Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) -Tissue retraction for Impression -Vestibuloplasty -Light activation of bleaching materials for teeth whitening -Laser-assisted bleaching / whitening of teeth	-Oral Papillectomy -Removal of Fibromas -Exposure of unerupted teeth -Soft Tissue Crown Lengthening -Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) -Tissue retraction for Impression -Vestibuloplasty -Light activation of bleaching materials for teeth whitening -Laser-assisted bleaching / whitening of teeth	-Oral Papillectomy -Removal of Fibromas -Exposure of unerupted teeth -Soft Tissue Crown Lengthening -Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) -Tissue retraction for Impression -Vestibuloplasty -Light activation of bleaching materials for teeth whitening -Laser-assisted bleaching / whitening of teeth

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 1 2010

Discus Dental, LLC
% Mr. Clark D. vonAhsen
Regulatory Affairs
8550 Higuera Street
Culver City, California 90232

Re: K102639
Trade/Device Name: SL3
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 18, 2010
Received: November 24, 2010

Dear Mr. vonAhsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: SL3

Indications for Use:
The SL3 laser is to provide the ability to perform intraoral soft tissue dental, general, oral maxilla-facial and cosmetic surgery. The SL3 laser is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a contact fiber optic delivery system.

The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, genecology, urology, opthamology and pulmonary surgery. The following are the oralpharngeal indications for use for which the device will be marketed:

-Excision and Incision Biopsies
-Hemostatic assistance
-Treatment of Apthous Ulcers
-Frenectomy
-Frenotomy
-Gingival Incision and Excision
-Gingivectomy
-Gingivoplasty
-Incising and Draining of Abscesses
-Operculectomy
-Oral Papillectomy
-Removal of Fibromas
-Soft Tissue Crown Lengthening
-Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
-Tissue retraction for Impression
-Vestibuloplasty
-Light activation of bleaching materials for teeth whitening
-Laser-assisted bleaching/whitening of teeth

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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